

## **Executive Summary**

### **International Initiative for Traumatic Brain Injury Meeting**

Vancouver, Canada

October 17-18, 2013

Following the International Initiative for Traumatic Brain Injury (InTBIR) meeting in Brussels in 2011, the three founding agencies, the European Commission's Health Directorate, the NIH's National Institute of Neurological Disorders and Stroke, and Canada's CIHR – Institute of Neurosciences, Mental Health and Addiction, agreed to several common objectives. One of these was to support new research in the field of TBI. To that end over the past two years all three agencies have independently launched a number of funding opportunities now supporting more than a dozen new projects focused on basic and clinical TBI research, representing a total investment of more than \$90M USD.

InTBIR is a unique consortium of funding agencies focused on improving clinical outcomes and lessening the global burden of TBI by 2020. Successful research projects will examine causal relationships between treatments and clinically meaningful outcomes ([http://www.thelancet.com/journals/lanneur/article/PIIS1474-4422\(12\)70166-7/fulltext](http://www.thelancet.com/journals/lanneur/article/PIIS1474-4422(12)70166-7/fulltext)). InTBIR activities are designed to accelerate scientific and clinical progress in TBI research through enhanced communication, coordination and collaboration. Through an international, multidisciplinary collaborative endeavour InTBIR hopes to find better diagnostics and effective therapies to reduce the global burden of TBI by 2020.

The two-day meeting in Vancouver in October, 2014 began with a review of the progress to date towards achieving the goals and objectives of InTBIR. Since a key objective of the meeting was to encourage scientific exchange and networking among members of the newly funded TBI research programs undertaken in the EU, the US and Canada, the meeting Agenda focused largely on scientific content for the first day, included a moderated session on the morning of the second day to address key opportunities, gaps and challenges, and a closed session at the end of the second day to enable further informal networking among the Principle Investigators.

This InTBIR meeting also provided attendees with an opportunity to learn more about existing and planned resources, including infrastructure, databases, Common Data Elements and their harmonization. Several critical issues pertaining to data sharing policies and technologies were addressed in a dedicated session intended to foster progress towards standardized data collection, sharing and meta-analyses. Overall there was a good consensus among PIs regarding the need for using CDEs and developing a data-sharing policy and infrastructure, and a voiced willingness to undertake the task.

The meeting also incorporated ethics and patient perspectives and gave participants the opportunity to hear from other funding agencies and organizations about support of TBI research in their countries. A presentation from Australia's Institute of Safety, Compensation and Recovery Research (ISCRR) focused on the rehabilitation portion of the TBI spectrum. The final formal session on Friday reflected on progress to date and highlighted some visions for the future, including input from the International Scientific Advisory Board.

Major recommendations from the 2013 InTBIR meeting include:

- The creation of a dedicated website for InTBIR to facilitate communication and collaboration. Progress since the meeting has been made.: the Federal Interagency TBI Research ([FITBIR](#)) team has been approached and they they are currently building a website for InTBIR that would link to FITBIR and other relevant websites.
- Strongly encourage all of the InTBIR studies to use the International TBI Common Data Elements ([CDEs](#)) to the greatest extent possible to enable data sharing in the future. Progress includes:
  - The Principle Investigators of the TRACK-TBI, ADAPT, CENTRE-TBI, and CENC studies are finalizing and sharing their CRFs to promote standardization across these four large studies that span a wide range of ages, times from injury, severities, and countries.
  - The Canadian project to develop CDEs for pediatric TBI includes Workgroup members from the U.S.-based Pediatric TBI CDE Project to ensure alignment.
  - [One Mind for Research](#) is providing funding for the Clinical Data Interchange Standards Consortium ([CDISC](#)) to format the International TBI CDEs so that they can be used for future clinical trials and validation studies that require U.S Food and Drug Administration ([FDA](#)) approval.
- Encourage a strong commitment to data sharing and facilitate the development of a common platform. The next step is to compare the FITBIR and the [Ontario Brain Institute](#), and the EU data sharing policies to see if they are compatible and would allow for federation of the informatics systems.
- Explicitly state the primary hypotheses of the individual InTBIR studies to ensure that the case report forms (CRFs) capture the needed information and to facilitate synergy across studies when the research questions converge. The next step is to prepare a summary table of the projects with this information and post it on the InTBIR website and also present this information at the next meeting.
- Develop strategies for effective communication between the program staff of the funding agencies, the investigators, the TBI community, and bioinformatics experts in order to meet the goals of InTBIR. Progress includes building a website (see above), monthly calls between funding agency program directors, and plans to convene additional meetings in 2014.
- Clarify expectations for new members and a process for joining InTBIR. The InTBIR program directors will draft a policy document to address this need and distribute it among the current members for approval.